In the United States Court of Federal Claims

No. 15-1549C

(E-Filed **UNDER SEAL**: September 2, 2022)
(Reissued: September 14, 2022)[1]

UNIVERSITY OF SOUTH FLORIDA, BOARD OF TRUSTEES, Plaintiff, v. THE UNITED STATES, Defendant.	Trial; Patent Infringement; 35 U.S.C. § 202(c)(4); Bayh-Dole Act; Paid-Up License; Affirmative Defense.

Steven B. Kelber, Bethesda, MD, for plaintiff. Jerry Stouck, Rockville, MD, of counsel.

Walter W. Brown, Senior Litigation Counsel, with whom were Brian M. Boynton, Principal Deputy Acting Assistant Attorney General, and Gary L. Hausken, Director, Commercial Litigation Branch, Civil Division, United States Department of Justice, Washington, DC, for defendant. Joshua I. Miller, Carrie E. Rosato, and Brian N. Gross, of counsel.

OPINION

CAMPBELL-SMITH, Judge.

In this patent dispute, plaintiff filed suit alleging that defendant infringed its patent by allowing a third party to use and manufacture the invention described in its patent. See ECF No. 1 (complaint). The court held trial in this matter in December 2021, after

[1] This opinion was filed under seal on September 2, 2022. See ECF No. 286. The parties were invited to identify source selection, propriety, or confidential material subject to deletion on the basis that the material is protected or privileged. No redactions were proposed by the parties. See ECF No. 288 (notice). Thus, the sealed and public versions of this opinion are identical, except for the publication date and this footnote.

which the parties filed post-trial briefing.[2] See ECF No. 274 (plaintiff's post-trial brief); ECF No. 279 (defendant's post-trial brief); ECF No. 280 (plaintiff's post-trial reply brief). This case has now been fully heard and is ripe for decision.

The court has considered all of the evidence and the parties' arguments and addresses the issues that are pertinent to the court's ruling in this opinion. Based on the evidence presented at trial, and for the following reasons, the court finds that defendant held a license pursuant to the Bayh-Dole Act, 35 U.S.C. § 202(c)(4), and is thus not liable for infringement of plaintiff's patent. The court, therefore, enters judgment in defendant's favor.

I. Findings of Fact

A. Patent Overview

Plaintiff holds the rights to United States Patent Number 5,898,094 (the '094 patent), which is titled "Transgenic Mice Expressing APPK670N,M671L and a Mutant Presenilin Transgenes." ECF No. 282-1 at 1 (joint exhibit 1). The '094 patent issued on April 27, 1999. See id. The patent involves "[a] method of preparing a transgenic animal model with enhanced, accelerated pathology for Alzheimer's Disease." Id. The patent notes that "[t]ransgenic model systems are needed to study neurodegenerative disorders, both to understand the underlying disease pathology as well as to test treatment protocols." Id. at 4.

In more concrete terms, the patent "showed people how to make a good, robust mouse model of Alzheimer's disease," ECF No. 270 at 42 (testimony of Dr. Karen Duff), by crossing mice with specific genetic mutations so that they would develop "enhanced" Alzheimer's pathology at an "accelerated" pace, id. at 45. The mice produced by using

[2] In addition to the post-trial briefs, the court considered the trial transcript, see ECF No. 270; ECF No. 271; ECF No. 272; ECF No. 273, and all of the exhibits introduced by the parties, including those filed on the docket in this matter, see ECF No. 282 (notice and exhibits), ECF No. 283 (corrected notice). The court notes that the official trial record is the trial transcript and the exhibits admitted at trial as recorded therein. The clerk's office, however, does not as a matter of practice include trial exhibits when it uploads trial transcripts to the court's case management/electronic case filing system; the court, therefore, requested that the parties upload the relevant exhibits for ease of access and clear citation in this opinion. Notwithstanding that request, the official record remains the trial transcript. The court further notes that the court reporter received the exhibits electronically from the parties during trial, and again after trial. The court understands that there was an administrative issue between the parties and the court reporter regarding the exhibits that delayed their transmission to the clerk's office and the transcript was transmitted prior to the exhibits. The court delayed release of this opinion for a time while awaiting the resolution of that issue.

the methods outlined in the patent are thus of utility in the research of Alzheimer's Disease and other neurodegenerative disorders. See ECF No. 282-1 at 4-5.

B. Patent Background

Dr. Karen Duff and Dr. John Hardy—named co-inventors on the patent, see id. at 1—were professors at the University of South Florida (USF) and worked together on research involved in the patent. See ECF No. 270 at 40, 44-45 (testimony of Dr. Duff); ECF No. 282-2 at 5-20 (joint exhibit 2, provisional patent application describing the research and desired outcomes). Dr. Duff and Dr. Hardy submitted a provisional patent application in October 1996 describing their research, which involved producing mice by:

> crossing one transgenic animal containing within its genome at least one copy of a first expressible wildtype or mutant mammalian transgene responsible for causing a particular Alzheimer's related pathology in humans with another transgenic animal containing [ ] within its genome at least one copy of a second expressible wildtype or mutant mammalian transgene also responsible for causing the particular Alzheimer's related pathology in humans to produce offspring containing within its genome at least one copy of both the first and second expressible wildtype or mutant mammalian transgenes responsible for causing the particular Alzheimer's related pathology in humans.

ECF No. 282-2 at 9; see also id. at 4 (date of the application).

The doctors, along with other researchers, also submitted an application to the National Institutes of Health (NIH) for grant funding in September 1995. See ECF No. 282-48 (defendant exhibit 59, grant application materials). The grant application sought funding for "five, mutually interlinking projects aimed at elucidating the role of the presenilins in Alzheimer's disease." Id. at 3. The proposed initial budget period for the grant was July 1, 1996, through June 30, 1997, and the application requested additional funding for four more years—five years of funding total. See id. at 12-14. On September 30, 1996, the NIH issued a National Institute on Aging program project grant, number 1P01AG014633 (AG014633) titled "Presenilins and Alzheimer's Disease," to the Mayo Clinic, where Dr. Duff and Dr. Hardy had taken positions. See ECF No. 282-42 (defendant exhibit 41, NIH grant materials); ECF No. 282-47 at 10 (defendant exhibit 56, notice of grant award); ECF No. 270 at 56 (testimony of Dr. Duff).

On April 25, 1997, Dr. Duff faxed a letter marked "urgent" to William Coppola in plaintiff's department dealing with patent applications detailing the process she and Dr. Hardy had engaged in and the results of their work. See ECF No. 282-28 (defendant exhibit 12, fax to Mr. Coppola); ECF No. 270 at 57-59 (testimony of Dr. Duff). This letter constituted the first documented evidence that the mice the inventors had been working on "did, indeed, develop pathology . . . at an age which was far accelerated."

ECF No. 270 at 59 (testimony of Dr. Duff); see also id. at 64 (Dr. Duff confirming that the letter was the "first documented evidence" she had of the mice). The doctors then submitted their patent application on July 30, 1997, and the patent is dated April 27, 1999. See ECF No. 282-1 at 1. The patent was assigned to plaintiff at that time. See id.

Dr. Duff and Dr. Hardy also published an article in Nature Medicine in January 1998 documenting the invention. See ECF No. 282-27 (def. exhibit 11). Dr. Duff testified at her deposition that "the invention actually became the 1998 Nature Medicine paper," ECF No. 282-62 at 70 (def. exhibit 439), though she testified at trial that she did not recall "which batches of animals were in the patent versus th[e] paper," and "whether they're exactly the same mice," she could not say, ECF No. 270 at 106. The article notes that the research documented therein was "supported by the Mayo/USF Program Project on the presenilins (AG146133)."[3] ECF No. 282-27 at 4.

C. Research Funding History

The research performed that resulted in the subject patent proceeded in multiple steps. See ECF No. 270 at 68-69 (testimony of Dr. Duff). Dr. Duff first had the "idea to create the[ ] mice" and "generated the presenilin mice," and then "was responsible for crossing [the] two mice together, for aging them . . . , and for discussing . . . exactly what would happen to those mice, making a decision on when to sacrifice them and . . . what procedures to perform on them." Id. at 69. Dr. Duff moved from USF to Mayo in December 1996 and "delegated" the immunohistochemistry work on the mice to Dr. Marcia Gordon's and Dr. David Morgan's lab at USF. Id. at 68. Immunohistochemistry is a "technique where you use an antibody, which is labeled with a dye, to identify the protein of interest in tissue sections . . . . [it] would have been applied to identify the amyloid plaques" in the tissue from the mouse brains. Id. at 65. The testing generated the proof of accelerated Alzheimer's pathology that was included in the fax that Dr. Duff sent as evidence of the pathology. See id. at 65-66 (Dr. Duff's testimony referencing Figure 1 included in the fax to William Coppola); ECF No. 282-28 at 3.

The work in Dr. Gordon's and Dr. Morgan's lab was included in the NIH grant application as Project Five, titled "Regulation and Function of the Presenilins in Rodent Brain." See ECF No. 282-29 at 208-09 (def. exhibit 17); see also id. at 212. Dr. Morgan is listed as the principal investigator and Dr. Gordon is listed as a co-principal investigator. See id. at 209. Dr. Gordon's role is described in the grant materials as "perform[ing] many of the histochemical procedures," and "play[ing] the major role in analyzing the histochemical data." Id. at 212. And, Dr. Morgan's role is described as "perform[ing] many of the surgical procedures," and "closely direct[ing] all experiments using molecular biological approaches." Id. The initial budget in the grant materials

[3] Dr. Duff testified that the grant number should have read "AG014633." See ECF No. 270 at 107.

specified that Dr. Morgan's and Dr. Gordon's salaries and fringe benefits would be paid in part with grant funds. See id. at 210.

Because Dr. Gordon and Dr. Morgan were located at USF and the grant funds ultimately were awarded to Mayo, see ECF No. 282-42 at 3, the funds were the subject of a consortium agreement—a subcontract—between the two entities, see ECF No. 282-5 at 2-7 (joint exhibit 8). Mayo signed the subcontract on November 5, 1997, and plaintiff signed on November 8, 1997. See id. at 7. The subcontract had an effective period of September 1, 1997, to August 31, 1998. See id. at 3. Plaintiff's proposal review and certification form indicates that plaintiff's internal account number for the funds was 6113-120-LO. See ECF No. 282-47 at 15; see also ECF No. 272 at 68 (testimony of Dr. Morgan). It also indicates that the project period was from September 1, 1996, through August 30, 1999, and the budget period was September 1, 1997, through August 30, 1998. See ECF No. 282-47 at 15. A second such form indicated the same project period and a budget period of September 1, 1998, through August 30, 1999. See id. at 13.

The parties presented no form for the first year of the project, from September 30, 1996, through August 30, 1997. See ECF No. 272 at 65-76 (testimony of Dr. Morgan discussing the forms). Dr. Morgan testified, however, that he "assumed" plaintiff "would have gotten funding prior to the start of year two." Id. at 75. He based that testimony on the forms and the grant award for the second year of the grant. See ECF No. 282-47 at 10; ECF No. 272 at 73-75. Dr. Morgan also reviewed a document that indicated that the "[t]he second year of the subcontract for NIH grant Account # 6113-127-LO closes August 31, 1998. This is a Mayo Clinic Subcontract Grant from the [NIH],"[4] ECF No. 282-47 at 7, and concluded that the first year of the subcontract would have been from September of [19]96 to August of . . . [19]97," ECF No. 272 at 76.

Dr. Morgan and Dr. Gordon both testified that Dr. Gordon was paid with funds from the NIH grant beginning October 1, 1996. See id. at 78-80 (testimony of Dr. Morgan); id. at 148-57 (testimony of Dr. Gordon). Both based their testimony on their understanding of Dr. Gordon's employment forms. See id.; see also ECF No. 282-46 at 1-14 (def. exhibit 51, Dr. Gordon's various employment forms). Dr. Gordon's employment contract notes that her appointment ran from October 1, 1996, through June 12, 1997, and was "funded through contract/grant Mayo Clinic, account # 6113120LO." ECF No. 282-46 at 14. It further states that her "employment ends with the expiration of this contract or the cancellation of the contract/grant, whichever occurs first." Id. The

[4] Trial testimony clarified that USF had two account numbers for the grant. See ECF No. 272 at 155-57 (testimony of Dr. Gordon). Dr. Gordon stated that "sometimes the university would give you a new account number for a new fiscal year of a grant . . . . It could be a completely different grant or it could be a different fiscal year of the same grant." Id. at 155. She did not recall working on any other grant tied to the Mayo Clinic. See id. at 157. The court thus concludes, based on the testimony and the statement in the document, that both account numbers reflect the Mayo Clinic subcontract grant.

contract was signed by plaintiff's representative on October 22, 1996, and was signed by Dr. Gordon on May 2, 1997. See id. Likewise, Dr. Gordon's appointment change form listed her appointment date as October 1, 1996, and the end date as June 12, 1997, with her salary being paid out of account number 6113120LO—the Mayo grant account number. See id. at 12. And, her appointment status form lists the same appointment dates, the same payment account, and a preparation date of December 16, 1996. See id. at 10. A second appointment status form with a preparation date of June 2, 1997, lists Dr. Gordon's appointment dates as January 1, 1997, through June 12, 1997, and the same Mayo grant payment account number. See id. at 9.

Dr. Gordon testified that her position at the time was grant-funded—her salary had to be supported by "funding from a grant." ECF No. 272 at 150. She stated that she did not recall working on any Mayo Clinic grant other than the one awarded by NIH. See id. at 157. She also testified that the delay in her signature on her employment contract was a result of "[u]niversity bureaucracy at its finest," because the contract was awaiting the signature of the university president for six months after the human resources person signed it. Id. at 150. But, she noted, she would have been paid even while the contract was pending signature, and her salary would have come from the Mayo grant. See id. at 151. Dr. Gordon explained that "if the grant was funded and awarded, . . . even if the physical check hadn't come from the NIH yet . . . there was a system of underwriting . . . so [USF] would underwrite certain things, and the would include salary, and then the university would recoup those funds once the physical . . . check was actually deposited." Id. at 156.

Dr. Morgan's testimony agreed with Dr. Gordon's as to her employment documents, and he also noted that plaintiff would have been charging expenses and salaries to the Mayo grant by "late 1996," and that "it's plausible that [he] would have also requested an underwrite at that time." Id. at 77. Dr. Morgan explained further that Dr. Gordon would have been paid under the subcontract as of October 1996, "or else there were 'rets' that were prepared to retroactively charge for salary that was paid from another source for that," meaning that "the department may have essentially subsidized her for some period of time, and then the grant was charged once . . . the subcontract was finalized for that purpose." Id. at 79. Dr. Morgan concluded that "because [they] were working on that project, and that was the first year of the grant, [ ] starting in September of 1996," and "because there was an account number that it stated as paying for her salary," it made sense to him that Dr. Gordon was paid under the Mayo subcontract. Id. at 80. He further stated that his recollection, although without documentation, was that plaintiff "had funds by December [1996] that we were using in order to pay for the mouse costs and pay for the reagents that we used. . . . And people's salaries as well." Id. at 94; see also id. at 120-21 ("[W]hat I would have assumed I would have done, is that once I learned from the Mayo Clinic that they had received the notice of award from the NIH . . . . I would have gone to USF and requested that they provide an advance on that award . . . . [W]e were very dependent financially upon this project.").

II. Legal Standards

The Bayh-Dole Act requires that a funding agreement between the United States and a nonprofit organization include a provision stating that "[w]ith respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world." 35 U.S.C. § 202(c)(4). The Act defines "funding agreement" as "any contract, grant, or cooperative agreement entered into between any Federal agency . . . and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government. Such term includes any . . . subcontract of any type." 35 U.S.C. § 201(b). It further defines "subject invention" to mean "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement." Id. § 201(e). Thus, the Act "vests in the government the right to a paid-up license to practice the invention when the contractor elects to retain title." Campbell Plastics Eng'g & Mfg., Inc. v. Brownlee, 389 F.3d 1243, 1247 (Fed. Cir. 2004).

Defendant may raise the existence of a license as a defense when it is sued for patent infringement. See Tech. Dev. Corp. v. United States, 597 F.2d 733, 746 (Ct. Cl. 1979); see also Madey v. Duke Univ., 413 F. Supp. 2d 601, 611 (M.D.N.C. 2006) ("[C]ourts have recognized that the license may be raised by the Government as an affirmative defense when the Government is sued for patent infringement in the Court of Federal Claims."). To successfully raise the defense, defendant "must establish by a preponderance of the evidence that a conception or a first actual reduction to practice occurred in the performance of a Government contract." Tech. Dev. Corp., 597 F.2d at 746 (citation omitted). If it does so, defendant is "not liable for royalties for any uses of that invention within the scope" of the license. Madey, 413 F. Supp. 2d at 612.

To prove the defense by a preponderance of the evidence, defendant must prove that "'the existence of a fact is more probable than its nonexistence.'" Ortiz v. Principi, 274 F.3d 1361, 1365 (Fed. Cir. 2001) (quoting In re Winship, 397 U.S. 358, 371-72 (1970)). In other words, a preponderance "'describe[s] a state of proof that persuades the factfinders that the points in question are more probably so than not.'" Id. (quoting Mueller & Kirkpatrick, Evidence § 3.3 (1995)) (emphasis removed). It is "the greater weight of the evidence, evidence which is more convincing than the evidence which is offered in opposition to it." Hale v. Dept. of Transp., F.A.A., 772 F.2d 882, 885 (Fed. Cir. 1985).

III. Analysis

The court is persuaded that the greater weight of the evidence demonstrates that defendant has a license to the '094 patent, and thus has successfully asserted an

affirmative defense to plaintiff's claim. Specifically, the court is persuaded that the evidence shows that the subject invention was first reduced to practice while the inventors were working pursuant to a funding agreement. See 35 U.S.C. § 202(c)(4); see also id. §§ 201(b), 201(e).

A. The '094 Patent Was First Reduced to Practice in April 1997

The parties agree, and the evidence demonstrates, that the invention described in the '094 patent was first reduced to practice in April 1997. See ECF No. 274 at 31 (plaintiff stating that the "first actual reduction to practice is reflected in the letter written by Karen Duff . . . on April 25, 1997"); ECF No. 279 at 10 (defendant stating that it "agrees with [plaintiff] that its first actual reduction to practice occurred in April 1997").

The evidence introduced at trial shows that on April 25, 1997, Dr. Duff faxed a letter to plaintiff's department handling patent matters detailing the process she and Dr. Hardy had engaged in to create the mice that were eventually documented in the '094 patent, and the results of their work. See ECF No. 282-28 (fax from Dr. Duff to Bill Coppola). And the trial testimony established that this constituted the first documented evidence that the mice the inventors had been working on "did, indeed, develop pathology . . . at an age which was far accelerated." ECF No. 270 at 59 (testimony of Dr. Duff); see also id. at 64 (Dr. Duff confirming that the fax was the "first documented evidence" of the mice).

The court thus concludes that the invention detailed in the '094 patent was first reduced to practice in April 1997.

B. Plaintiff Was Using NIH Grant Funds as Early as October 1996

Defendant argues in its post-trial brief that NIH program project grant AG014633 funded plaintiff's first reduction of the invention to practice. See ECF No. 279 at 10-14. Plaintiff, however, contends that no grant funds flowed to plaintiff until the formal subcontract between the Mayo Clinic and plaintiff was signed in November 1997. See ECF No. 274 at 32-33; ECF No. 280 at 8-11. According to plaintiff, it "paid for the work on the mice of the '094 Patent up to, through and beyond April 25, 1997." ECF No. 280 at 8 (emphasis in original). And, plaintiff contends, four witnesses testified "the only way for money to have flowed to [plaintiff] from the NIH grant in question . . . would have been for a subcontract to be entered into between Mayo Clinic . . . and [plaintiff]." ECF No. 274 at 32 (emphasis in original).

The evidence, however, shows that plaintiff paid for the work done by Dr. Gordon at USF with the NIH grant funds. The trial record demonstrates that plaintiff assigned account number 6113-120-LO to the grant funds that came from NIH to the Mayo Clinic and then to plaintiff. See ECF No. 282-47 at 15; see also ECF No. 272 at 68 (testimony

of Dr. Morgan). Trial testimony also established that Dr. Gordon was paid with funds out of that account beginning October 1, 1996. See ECF No. 272 at 78-80 (testimony of Dr. Morgan); id. at 148-57 (testimony of Dr. Gordon). Dr. Gordon's employment documents likewise indicate that she was paid with funds out of plaintiff's grant account for an appointment term beginning in October 1996. See ECF No. 282-46 at 10, 12, 14.

Specifically, trial testimony revealed that Dr. Gordon would have been paid under the subcontract as of October 1996, "or else there were 'rets' that were prepared to retroactively charge for salary that was paid from another source for that," meaning that "the department may have essentially subsidized her for some period of time, and then the grant was charged once . . . the subcontract was finalized for that purpose." ECF No. 272 at 79 (testimony of Dr. Morgan). Dr. Morgan, a principal investigator on the grant and specifically for the project being conducted at USF, concluded that "because [he and Dr. Gordon] were working on that project, and that was the first year of the grant, [ ] starting in September of 1996 . . . . And . . . because there was an account number that it stated as paying for her salary," it made sense to him that Dr. Gordon was paid under the NIH grant by the Mayo Clinic subcontract. Id. at 80.

The greater weight of the trial testimony also established that plaintiff was using NIH funds by December 1996 to pay for costs associated with conducting the immunohistochemistry work that was a key part of the research that led to the '094 patent. See id. at 94 (Dr. Morgan testifying that his recollection, although without documentation, was that plaintiff "had funds by December [1996] that we were using in order to pay for the mouse costs and pay for the reagents that we used . . . [a]nd people's salaries as well"); see also id. at 120-21 (Dr. Morgan testifying, "what I would have assumed I would have done, is that once I learned from the Mayo Clinic that they had received the notice of award from the NIH . . . . I would have gone to USF and requested that they provide an advance on that award . . . . [W]e were very dependent financially upon this project.").

The court finds the testimony of Dr. Morgan and Dr. Gordon credible and is persuaded "that the points in question are more probably so than not.'" Ortiz, 274 F.3d at 1365 (quoting Mueller & Kirkpatrick, Evidence § 3.3 (1995)). The court therefore concludes that the evidence establishes that plaintiff's work on the mice in the '094 patent was performed using funds from NIH grant AG014633 as early as October 1996.

C. Plaintiff Performed the Work on the '094 Patent Pursuant to an Implied Subcontract with the Mayo Clinic

The trial record establishes that, beginning in October 1996, plaintiff operated pursuant to an implied contract with the Mayo Clinic for grant funds under the NIH AG014633 grant. Plaintiff argues that "[t]here simply never was an implied subcontract between [plaintiff] and Mayo Clinic." ECF No. 280 at 8. According to plaintiff, because

there was an express subcontract between plaintiff and the Mayo Clinic that was signed in November 1997, there "could not have been an implied contract." Id. at 11. Defendant contends, however, that "[w]hen the evidence is viewed properly, it is clear that an implied contract existed between USF and Mayo at the time of the April 1997 actual reduction to practice," because "the conduct of the parties indicated that a subcontract existed," given that Dr. Gordon's salary was paid out of grant funds. ECF No. 279 at 16.

"[A]n implied-in-fact contract is one 'founded upon a meeting of minds, which, although not embodied in an express contract, is inferred, as a fact, from conduct of the parties showing, in the light of the surrounding circumstances, their tacit understanding.'" Atlas Corp. v. United States, 895 F.2d 745, 754 (Fed. Cir. 1990) (quoting Porter v. United States, 496 F.2d 583, 590 (Ct. Cl. 1974)). In the court's view, such a contract existed between plaintiff and the Mayo Clinic.

As the court determined above, trial testimony established that Dr. Gordon was paid out of plaintiff's internal account for the grant funds. See ECF No. 272 at 78-80 (testimony of Dr. Morgan); id. at 148-57 (testimony of Dr. Gordon). Regardless of whether plaintiff underwrote those funds for a time before money flowed from the Mayo Clinic, it is clear in the record that plaintiff had a "tacit understanding" with Mayo that the funds would eventually arrive. Atlas Corp., 895 F.2d at 754; see also, e.g., ECF No. 272 at 120-21 (Dr. Morgan testifying, "what I would have assumed I would have done, is that once I learned from the Mayo Clinic that they had received the notice of award from the NIH . . . . I would have gone to USF and requested that they provide an advance on that award . . . . [W]e were very dependent financially upon this project."). And plaintiff was using grant funds as early as October 1996 to fund the immunohistochemistry work that contributed to the '094 patent.[5] See ECF No. 282-46 at 10, 12, 14 (Dr. Gordon's employment documents reflecting payment of her salary out of the grant account beginning October 1, 1996). The court thus finds that the conduct of the parties (plaintiff's creating a grant account and charging Dr. Gordon's salary to the account), in light of the surrounding circumstances (the grant having been awarded in September 1996 and testimony that plaintiff was financially dependent on the award, see ECF No. 272 at 121), indicates plaintiff's and Mayo's "tacit understanding" that grant funds would flow from the NIH to the Mayo Clinic and ultimately to plaintiff. Atlas Corp., 895 F.2d

[5] Plaintiff argued that the work done at USF by Dr. Gordon and Dr. Morgan was to "document behavior in presenilin rodents, not to make new genetic variants." ECF No. 274 at 34. The court cannot credit this argument in light of trial testimony that established that the USF doctors did immunohistochemistry work pursuant to the grant project, and that immunohistochemistry was the testing that generated the proof of accelerated Alzheimer's pathology. See ECF No. 270 at 65-66 (Dr. Duff's testimony referencing Figure 1 included in the fax to William Coppola); ECF No. 282-28 at 3. This testing appears to the court to be integral to the project, especially so because it was included in the fax that Dr. Duff sent as evidence of the pathology. See id.

at 754. The court therefore holds that the Mayo Clinic and plaintiff entered into an implied subcontract on October 1, 1996, which is the same date as Dr. Gordon's appointment as documented in her employment forms. See ECF No. 282-46 at 10, 12, 14.

D. Defendant Held a Paid-Up License Pursuant to the Bayh-Dole Act

The Bayh-Dole Act requires that a funding agreement between the United States and a nonprofit organization include a provision providing that "[w]ith respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world." 35 U.S.C. § 202(c)(4). This court has held that "where a patentee has been intimately involved in all phases of performance of a Government-funded contract during the performance of which the invention was conceived and/or first actually reduced to practice, and the work was, in fact, paid for in substantial part or entirely out of Government funds, the Government is entitled to a license." Tech. Dev. Corp., 597 F.2d at 746. To establish its right to a license, therefore, defendant must demonstrate that there was a funding agreement in place at the time the '094 patent was conceived or first reduced to practice.

The court finds here that defendant has met its burden and has demonstrated that the work on the '094 patent meets the terms of Bayh-Dole Act such that defendant held a license. As an initial matter, the work was performed pursuant to a funding agreement. The trial record established that plaintiff and the Mayo Clinic entered into an implied subcontract beginning in October 1996 with respect to grant funds awarded by the NIH. See supra Sections III.B. and III.C. The Act defines a funding agreement to include "any contract, grant, or cooperative agreement entered into between any Federal agency . . . and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government. Such term includes any . . . subcontract of any type." 35 U.S.C. § 201(b). Thus, the subcontract between Mayo and plaintiff is considered a funding agreement.

Further, the trial record established that the '094 patent constitutes a "subject invention" because it was first actually reduced to practice in April 1997, during the course of performance of work under the grant. See id. § 201(e); see also supra Sections III.A, B, and C (determining that the patent was first reduced to practice in April 1997 and that the grant subcontract began in October 1996).

The court thus concludes that plaintiff was "intimately involved in all phases of performance," and the work performed by plaintiff "was, in fact, paid for in substantial part or entirely out of Government funds." Tech. Dev. Corp., 597 F.2d at 746. Defendant is therefore entitled to a "nonexclusive, nontransferrable, irrevocable, paid-up

license" to practice the '094 patent. 35 U.S.C. § 202(c)(4). As such, defendant is not liable for infringement of the patent, and the court need not reach the parties' arguments as to prior invention, obviousness, or damages. See Madey, 413 F. Supp. 2d at 612 ("If the Government meets this burden, the Government is not liable for royalties for any uses of that invention within the scope of the Government License."). Plaintiff's claims are denied.

IV. Conclusion

Accordingly, for the foregoing reasons:

(1) The clerk's office is directed to **ENTER** final judgment in defendant's favor; and

(2) On or before **September 23, 2022**, the parties are directed to **CONFER** and **FILE** a **notice** attaching the parties' agreed-upon redacted version of this opinion, with all competition-sensitive information blacked out.

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
PATRICIA E. CAMPBELL-SMITH
Judge